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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,477	08/22/2006	Torsten Branderburger	05116835	1954

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EXAMINER	
MARCETICH, ADAM M	

ART UNIT	PAPER NUMBER
3761	

NOTIFICATION DATE	DELIVERY MODE
03/11/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@mayerbrown.com

Office Action Summary	Application No.	Applicant(s)	
	10/550,477	BRANDERBURGER ET AL.	
	Examiner	Art Unit	
	ADAM MARCETICH	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 25 June 29010 has been entered.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). A certified copy of parent Application No. Germany 103 13 760.2, filed on 27 March 2003 has been received.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1, 2, 10, 11, 12 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strobel; Michael (US 6723076) in view of Imer; Rodney H. (US 5228782).

6. Regarding claims 1 and 11, Strobel discloses a connector for packings containing medical liquids, particularly infusion, transfusion or enteral bags (col. 1, lines 5-10, 39-47, cols. 64-6, Fig. 1, system 1), comprising:

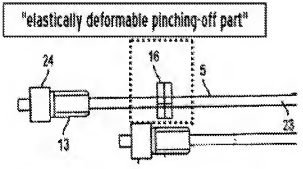
a connecting part with a passage capable of accommodating a rod or a spike for filling or withdrawal of liquid (col. 4, lines 38-40, col. 5, lines 30-34, Fig. 1, delivery tube 5 having lumen and therefore capable of accommodating rod or spike);

a closure part which can be fitted onto the connecting part and closes the passage in the connecting part (col. 5, lines 1-5, 21-29, Fig. 1, cap 24);

characterized in that the connecting part has an elastically deformable pinching-off part (portion of delivery tube 5; see annotated Fig. 1 of Strobel);

which re-assumes its original shape again after being pinched by a pinching device (col. 5, lines 62-67, Fig. 1, clamp 16 deforming delivery tube 5, which later re-assumes its original shape); and

a pinching-off part that merges into a base part which widens to both sides and which can be integrated in the packing (col. 5, lines 14-21, delivery tube 5 connected to opening 22, depicted as having a larger diameter and therefore widened to both sides).



Annotated Fig. 1 of Strobel: Michael (US 6723076)

7. Strobel discloses the invention substantially as claimed, including a pinching-off part (portion of delivery tube 5). However, Strobel lacks a pinching-off part with a noncircular axial cross section. Imer discloses a resealable satchet for liquids (col. 1, lines 5-11, col. 2, lines 61-68, Fig. 1, satchet 1), comprising:

a connecting part (col. 3, lines 2-15, Fig. 1, opening strap 4);

with a passage (col. 3, lines 2-15, Fig. 1, outlet channel 3.1); and

a pinching-off part (col. 3, lines 20-27, Fig. 1, folding line 7);

that is designed as a tubular portion with a noncircular axial cross section that is different in two mutually perpendicular directions (col. 3, lines 28-31, portion of strap 4 near folding line 7 having substantially flat and noncircular axial cross section).

Imer solves the problem of containing and dispensing liquid from a bag with a resealable connection. Both Strobel and Imer dispense liquid through tubing attached to a bag, and use clamping mechanisms. Strobel applies clamp 16 to the outside of tube 5

(col. 5, lines 56-61), and Imer holds a folded portion of opening strap 4 within holding slit 6 (col. 3, lines 20-27).

8. Imer effectively clamps the portion of opening strap 4 within slit 6, to hold fluid within inner section 3 (col. 45, lines 12-18, especially lines 18-19, fold preventing leaks). A flat shape, or noncircular axial cross section prevents leaks through a clamped tube, since both surfaces of the tube contact each other when closed. In other words, a noncircular axial cross section is adapted for repeated clamping. One would be motivated to modify Strobel with the noncircular axial cross section as taught by Imer to hold fluid in a clamped state since Strobel calls for repeatedly clamping delivery tube (col. 5, lines 56-67, selective coupling to injection system). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Strobel as discussed with the noncircular axial cross section as taught by Imer in order to provide tubing or a connecting part adapted for clamping and resealing.

9. Strobel and Imer disclose the invention as substantially claimed but are both silent whether the connecting part is also "an injection-molded component." Instead, Strobel and Imer are silent regarding the manufacturing processes that form delivery tube 5 and folding line 7. Examiner finds that injection-molding technologies are also capable of producing the same structure of either Strobel or Imer, since injection molding can produce tubes or films. That is, there is no patentable difference between the pinching-off parts of Strobel and Imer.

10. This rejection is made in light of ***In re Thorpe***, 227 USPQ 964 (CAFC 1985) wherein product-by-process claims to a pinching-off part are rejected over folding line 7 of Imer which although may be prepared in a different manner, appears to be the same (prima facie) as the claimed product and performs the same function as the claimed product does.

11. The specification describes both the connecting and closure parts as injection-molded polypropylene components (p. 6, lines 1-2) and calls for a pinching-off part with a non-circular cross section that can be deformed easily without breaking (p. 6, lines 4-14). However, the specification does not describe additional structures that would patentably distinguish from the pinching off part of Strobel and Imer. Tubes of indeterminate length as in Strobel are generally formed by extrusion, and foils or sheets of indeterminate area can be formed by blown film extrusion. However, both of these processes would also produce easily deformed, durable pinching-off parts. Thus, even though Strobel and Imer are silent as to the process used to form a pinching-off part, it appears that the product as taught by Imer would be the same or similar as that claimed; especially since both applicant's product and the prior art product require a durable, flexible plastic pinching-off part. See MPEP 2113.

12. Regarding claims 2, 10, 12 and 20, Strobel discloses:

a closure part and connecting part secured with a snap fit (col. 5, lines 21-29, cap 24 for closing tube 5); and

a packing for medical liquids, particularly an infusion, transfusion or enteral bag, having at least one connector as claimed in claim 1 (col. 1, lines 5-10, bag for fluid medications or nutrients).

13. Claims 3, 5, 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strobel; Michael (US 6723076) in view of Imer; Rodney H. (US 5228782), further in view of Fowles; Thomas A. et al. (US 4632267).

14. Regarding claims 3 and 13, Strobel and Imer disclose the invention substantially as claimed, but lack a self-sealing membrane. Instead, Strobel discloses that connectors 12 and 13 are luer or twist-type connectors (col. 4, lines 54-60, col. 5, lines 30-34).

Fowles discloses a connector for packings containing parenteral and peritoneal dialysis liquids (col. 1, lines 4-17, col. 2, lines 50-58, Figs. 1-3, port system); comprising:

a connecting part with a passage (col. 2, lines 50-58, Fig. 1, port 13 having lumen);

which can accommodate a rod or a spike for filling or withdrawal of liquid (col. 2, lines 66-3, Fig. 1, opening 22 for needle or other access means);

a closure part which can be fitted onto the connecting part and closes the passage in the connecting part (col. 2, lines 50-58, Fig. 1, closure 10);

a self- sealing membrane arranged between the connecting part and the closure part that can be pierced by the spike for withdrawal of the liquid (col. 2, lines 59-66, Fig. 1, partition wall 20 dividing tubular bore 18 into upper bore 19 and lower bore 21;

Examiner interprets the wall 20 as substantially "between" a connecting part and closure part, since it is narrower than the lumens of both closure 10 and port 13. additionally, wall 20 is between closure 10 and the lower bore 21 of port 13).

Fowles provides a connecting part adapted to be repeatedly pierced with a needle. Both Strobel and Fowles provide a detachable cap (cap 24 of Strobel and closure 10 of Fowles) at the end of a connecting part (delivery tube 5 of Strobel and port 13 of Fowles). Withdrawal needles are commonly interchanged as Luer-type connectors. That is, systems that couple lumens with Luer connectors or a membrane and needle are commonly interchanged. Additionally, a needle-membrane system preserves sterility by preventing contaminants from entering the outlet of a bag.

One would be motivated to modify Strobel and Imer with the self-sealing membrane as taught by Fowles to preserve the contents of a dispensing bag since Strobel calls for an adapter that is connected intermittently and excludes contaminants (col. 6, lines 43-49). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Strobel and Imer as discussed by substituting a needle-membrane system of Fowles for the Luer connectors of Strobel in order to couple to dispensers commonly used in the art, while excluding contaminants.

15. Regarding claims 5 and 15, Strobel and Imer disclose the invention substantially as claimed, but lack an annular break zone. Fowles discloses:

a closure part having a cap-shaped bottom part which is adjoined via an annular break zone (col. 3, lines 49-58, Fig. 2, scored line 150);

by a top part that can be broken off (Fig. 3, detached portion of closure 110).

Here, Fowles seals a cap initially before a user can withdraw fluid from a container. That is, the container is tamper-evident since scored line 150 is broken when first removing fluid from the container. Afterwards, the user can reseal the connector by replacing closure 10 on port 12. Fowles shows whether a container has been opened, and prevents contaminants from reaching the exterior surface of a piercing membrane. One would be motivated to modify Strobel and Imer with the annular break zone and top part as taught by Fowles since Strobel calls for a sealing cap 24 placed on adapter 13.

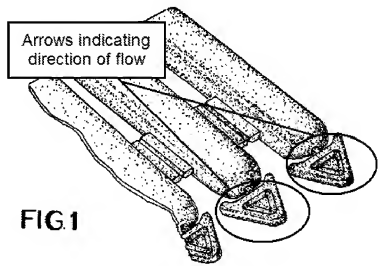
16. Claims 4 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strobel; Michael (US 6723076) in view of Imer; Rodney H. (US 5228782) in view of Fowles; Thomas A. et al. (US 4632267), further in view of Burns (US 5494170).

17. Regarding claims 4 and 14, Strobel, Imer and Fowles disclose the invention as substantially claimed, but lack clamping with elastic deformation between a connecting part and a closure part. Burns discloses a closure part and connecting part secured with a snap fit (column 2, lines 61-67 and column 3, lines 13-23, Fig. 1, cam ring 4 and cooperating cam follower ring 16 forming snap-fit), further comprising a self-sealing membrane held clamped with elastic deformation between a connecting part and a closure part (column 2, lines 53-58 and Fig. 1, stopper 12 depicted as held between tube 1 and shield 11). Burns provides the advantage of simple construction in addition to multiple withdrawals. Additionally, holding a membrane with elastic deformation allows a different material to be used for a sealing membrane which may be more

adaptable for repeated piercing. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Strobel, Imer and Fowles as discussed with the clamped, self-sealing membrane as taught by Burns in order to provide simple construction and multiple withdrawals.

18. Claims 6-8 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strobel; Michael (US 6723076) in view of Imer; Rodney H. (US 5228782) in view of Fowles; Thomas A. et al. (US 4632267), further in view of LeMarr et al. (US D456,507).

19. Regarding claims 6-8 and 16-18, Strobel, Imer and Fowles disclose the invention as substantially claimed, but lack a flat grip piece and an arrow designed as a recess and/or as a raised structure. LeMarr discloses a nebulizer vial comprising a flat grip piece and an arrow designed as a recess and/or as a raised structure (see annotated Fig. 1). LeMarr provides the advantage of showing a user where fluid will exit a container when opened. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention



Annotated Fig. 1 of LeMarr et al. (US D456507)

of Strobel, Imer and Fowles as discussed with the arrow as taught by LeMarr in order to instruct a user.

20. Claims 9 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strobel; Michael (US 6723076) in view of Imer; Rodney H. (US 5228782) in view of Fowles; Thomas A. et al. (US 4632267), further in view of Knierbein (US 6364143).

21. Regarding claims 9 and 19, Strobel, Imer and Fowles disclose the invention substantially as claimed, but lack a boat shape. Knierbein discloses a connector characterized in that the base part is designed in the shape of a boat (col. 3, lines 32-40 and Fig. 1, boat-shaped lower part 3 having boat-shape). Knierbein provides the advantage of effectively draining a liquid container. For example, a boat shape drains contents of a bag effectively when inverted. One would be motivated to modify Strobel, Imer and Fowles with the boat shape as taught by Knierbein to drain a liquid container effectively.

Response to Arguments

22. Applicant's arguments filed 25 June 2010 with respect to the rejection(s) of claim(s) 1-20 under 35 USC § 103 over Strobel, Imer, Fowles, LeMarr, Knierbein and Burns have been fully considered but are not persuasive. Therefore, the rejection is maintained. Examiner finds that the product-by-process limitation of amended claim 1 is obvious over Strobel and Imer.

23. Applicant contends that the rejections should be withdrawn since the references lack a connecting part "that is an injection-molded component." Examiner cites In re Thorpe and MPEP 2113 as supporting a rationale that an injection-molded component would have the same properties as the pinching-off part of Imer.

24. Applicant submits that motivation is lacking to modify Strobel in view of Imer, since the delivery tube of Strobel is already sufficiently flexible for clamping and an injection-molded part would normally be sufficiently rigid to preclude clamping. Examiner finds that the pinching-off part with a noncircular cross-section of Imer would enhance clamping, and have the same properties as an injection-molded component, especially flexibility and breakage resistance.

25. Applicant contends that Strobel teaches away from the present invention, since the user cannot puncture or insert an object into the bag, which would "destroy[] the sterility of the system." Examiner finds that delivery tube 5 of Strobel comprises a lumen and is therefore capable of accommodating a rod or spike. Additionally, modifying Strobel with a self-sealing membrane would not require a user to compromise sterility and would provide means of reconstituting fluid from an injection source.

Conclusion

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to:

Adam Marcetich
Tel 571-272-2590
Fax 571-273-2590
Email Adam.Marcetich@uspto.gov

27. The Examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

28. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

29. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/
Examiner, Art Unit 3761